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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,918

06/27/2003

John B. Harley

OMRF:050USD2

6316

7590

11/24/2006

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EXAMINER

LI, BAO Q

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,918	HARLEY ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed on 10/05/06. The abstract has been amended and accepted. Claims 1-5 have been amended. Claims 6-26 have been canceled. A new claim 27 has been added. Claims 1-5 and 27 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112 1st paragraph

1. Claims 1-5 are still rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enable for inducing an immune response by using an EBV peptide antigen that is not derived from the peptides PPPGRRP, GRGRGRGG and RGRGREK, does not reasonably provide enablement for using such peptide as a vaccine to prevent an autoimmune diseases associated with EBV infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. This is a new ground rejection necessitated by applicants' amendment.
2. Applicants submit that the claims are now amended to cite the polypeptide having the autoantigen removed, the ground of rejection therefore, should be removed.
3. Applicants' argument and amendment have been respectfully considered; however, it is not found persuasive. The broad scope of amended claims now still is drawn to a vaccine, which is rejected under 112 1st paragraph in the previous office action. Because specification fails to provide any evidence to support that any disclosed EBV polypeptide in the specification is able to be used as a vaccine to induce any protective immune response against any disease.
4. To this context, the previous 112 1st paragraph rejection is maintained.

Claim Rejections - 35 USC § 102

5. Claims 1-5 are still rejected under 35 U.S.C. 102(b) as being anticipated by Ambinder et al. (J. Virol. 1991, Vol. 65, No. 3, pp. 1466-1478) in view of the disclosure by Petersen et al. Arthritis and Rheumatism 1990, Vol. 33, No. 7, pp. 993-1000). This is a new ground rejection necessitated by the amendment of claims.

6. Applicants traverse the rejection and submit that the Ambinder et al. only teach a recombinant vectors or a plasmids encoding several truncated EBV nuclear antigen. They are nucleic acid molecules. There is no evidence indicating that epitopes of this EBV antigen polypeptide is able to react with an antibody against an autoantigen in an antigen, wherein said antigen are altered or deleted.

7. Applicants' argument has been respectfully considered; however, it is not found persuasive. Because Ambinder et al. not only teach the plasmid DNA comprising the truncated EBV nuclear antigen 1 (EBV-NA1) peptide antigen, but also the peptide antigens that are able to induce an immune response, wherein the truncated peptide antigen has a deletion from amino acid residue 390 to 547 or from 504 or 522 to 611 where the autoantigen epitopes PPPGRRP, GRGRGRGREKR or KGGWFCKMRC are located in view of the disclosure by Petersen et al. (Arthritis and Rheumatism 1990, Vol. 33, No. 7, pp. 993-1000, please see Figs. 1-5 and Table 1). Therefore, the claimed invention is still anticipated by the cited reference.

8. Claims 1-5 are still rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al. (J. Immunol. 1985, Vol. 134, No. 1, pp. 211-216) on the same ground as stated in the previous office action.

9. Applicants traverse the rejection and submit that the Rhodes et al. do not teach a polypeptide and the peptide taught by Rhodes et al. does indeed contain an epitope (poly-GA) that reacts with antibody against an autoantigen.

10. Applicants' argument has been fully considered; however, it is not found persuasive. Rhodes et al. do teach several EBV-NA derived peptides; some of them contain the epitopes of autoantigens, such as peptides F14, F15, P16 and p62, whereas others, like peptide antigens F12 and F13, do not contain any autoantigen's epitope. All of these peptide antigens are able to induce immune responses when they are administrated into rabbits in combination with a

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Freund's complete adjuvant (See entire document, pages 211-212 and specially Fig. 1, Table I & Table II). Therefore, the claimed invention is anticipated by the cited reference.

Conclusion

No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

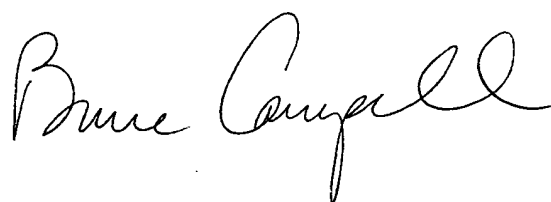
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Bao Qun Li

11/15/2006



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